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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,414	01/06/2005	Raju Adhikari	07082.0020U1	5460

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EXAMINER	
DICKINSON, PAUL W	
ART UNIT	PAPER NUMBER
4173	

MAIL DATE	DELIVERY MODE
11/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,414	ADHIKARI ET AL.	
	Examiner	Art Unit	
	Paul W. Dickinson	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/12/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *1-10,13,15-18 and 23-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,12,14 and 19-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/16/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, Claims 11-22 in the reply filed on 10/12/2007 is acknowledged. Applicant's election without traverse of the following is also acknowledged: methyl-2,6-diisocyanato hexanoate as the isocyanate, pentaerythritol as the low molecular weight multifunctional core, caprolactone as the soft segment monomer, and a biodegradable, biocompatible composition that does further comprise biological and inorganic compounds.

Claims 1-10, 13, 15-18, 23-32 are directed to a non-elected species and are hereby withdrawn. Claims 11-12, 14, and 19-22 are currently under consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by EP 0837084 (Document provided by Applicant; The document lacks pagination and the Examiner is considering the title page to be Page 1). '084 discloses biodegradable, biocompatible branched polymers containing dioxanone units that are optionally end-capped with isocyanate (see abstract; p 3, ln 34-43). These isocyanate end-capped polymers are formed by the reaction of an isocyanate with a low molecular weight multifunctional core

(see Example 9). The isocyanate end-capped polymers can be subsequently treated with alkylene oxide polymers, affording functional oligomers with pendant alkene oxide polymeric arms (see p 7, ln 13-17). An example is given wherein a star copolymer of p-dioxanone and glycolide is treated with lysine isocyanate (ethyl-2,6-diisocyanato hexanoate) (see Example 9). The resulting isocyanate end-capped star polymer is treated with poly(ethylene oxide monomethyl ether) (see Example 24).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12, 14, 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0837084 in view of US 3281378. As stated above, '084 discloses biodegradable, biocompatible branched polymers containing dioxanone units that are optionally end-capped with isocyanate. These isocyanate end-capped polymers are formed by the reaction of an isocyanate with a multifunctional core. The isocyanate end-capped polymers can be subsequently treated with alkylene oxide polymers, affording functional oligomers with pendant alkene oxide polymeric arms. The presence of these arms reduce cell adherence while maintaining the biodegradability of the polymer (see p 7, ln 16-17). '084 discloses that caprolactone and its related compounds are known in the art as components in surgical devices (see p 2, ln 38-40). The polymers disclosed by '084 can be administered as an *in-vivo* implant (see 6, ln 12-21) and a delivery vehicle for therapeutic agents, such as cross-linked dextran (see p 7, ln 18-39) or hydroxyapatite (see Examples 13-18).

'084 fails to disclose a biodegradable, biocompatible polymer composition comprising the reaction product of water, polycaprolactone triol and a prepolymer comprising the reaction product of pentaerythritol and methyl 2,6-diisocyanato hexanoate. '084 further fails to disclose a polymeric scaffold comprising a cured

polymer of the above material, including the physical properties (compressive strength and pore size) of such a material.

'378 discloses a polymer formed from the reaction of pentaerythritol with 2,6-diisocyanato propyl caproate (propyl 2,6-diisocyanato hexanoate) (see Example 17), 2,6-diisocyanato dodecyl caproate (dodecyl 2,6-diisocyanato hexanoate) (see Example 19), or 2,6-diisocyanato phenyl caproate (phenyl 2,6-diisocyanato hexanoate) (see Example 36). '378 discloses 2,6-diisocyanato methyl caproate (methyl 2,6-diisocyanato hexanoate) as a preferred reagent (see col 2, ln 3-44).

One skilled in the art would be motivated to combine the disclosures of '084 and '378 to afford the instant invention, with a reasonable expectation of success. Specifically, in the effort to manufacture improved biodegradable, biocompatible branched polymers and scaffolds made from such materials, it would be reasonable to produce a polymer made by reaction of pentaerythritol with methyl 2,6-diisocyanato hexanoate to afford an isocyanate end-capped polymer. To reduce cell adherence while maintaining the biodegradability of the polymer, the isocyanate end-capped polymer could be subsequently reacted with a biodegradable polymer. Owing to its precedent in the art in surgical devices, a good choice of biodegrable polymer would be polycaprolactone. It would be reasonable to use the resulting polymer as an *in-vivo* implant and a delivery vehicle for therapeutic agents, such as cross-linked dextran. Optimization of the compressive strength and pore size of the implant is not, in itself, patentable subject matter. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there

is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul W. Dickinson whose telephone number is 571-270-3499. The examiner can normally be reached on Mon-Thur 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul W Dickinson
Examiner
Art Unit 4173

November 28, 2007

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614